P.07

Application No. 10/044,354
Reply to Office Action dated August 11, 2004

Remarks

Applicant has carefully reviewed the Office Action mailed on February 3, 2005. Applicant respectfully traverses all objections, rejections, and assertions made by the Examiner. Claims 1-20, 26, 27, and 30-39 have been canceled, claims 23 and 29 have been amended, and claims 21, 22, and 28 remain withdrawn from consideration. Claims 21-25, 28 and 29 are pending, and claims 23-25 and 29 are examined. No new matter has been added.

Rejection under 35 U.S.C. § 103(a)

Claims 1-8, 10-20, 23-27, 29, and 30-39 are rejected as being unpatentable over Epstein et al. (5,951,589) in view of Dieck et al. (6,425,909). Applicant respectfully traverses the rejection. Independent claims 23 and 29 have been amended to recite the method step of actuating the expansion member so as to shift the filter frame from a generally collapsed configuration to a generally expanded configuration such that the filter material conforms to the blood vessel or renal artery lumen.

The entire disclosure of Epstein et al. is directed to a method for percutaneous occlusion of vascular access sites. That is, complete blockage of a vessel wall puncture rather than filtration where blood continues to flow. See column 1, line 11 through column 2, line 44. Epstein et al. teach a method in which the elongate member 22 is inserted through a puncture into a vessel lumen, the closure assembly 32 is deployed and the elongate member 22 is retracted until "the proximal surface of the flattened flexible membrane 36 is brought into close engagement with the inner surface of the wall 103 forming the lumen 104 in which the closure assembly 32 is disposed." See column 8, lines 20-24 and FIGS. 4, 5A-5D, and 24. Epstein et al. teaches the method as achieving a liquid tight seal between the closure assembly and the wall adjacent the puncture.

The device of Epstein et al. is not designed for and is not used in a way such that the impermeable membrane 36 conforms to the blood vessel lumen. Epstein et al. provides a device in which the impermeable membrane 36 is held against a puncture in the vessel wall to seal the puncture and allow a biological sealant to be applied. Epstein et al. thus do not teach or suggest the method steps recited in independent claims 23 and 29.

P.08

Application No. 10/044,354 Reply to Office Action dated August 11, 2004

Dieck et al. disclose devices and methods for filtering fluid flowing through a body structure such as a vessel. Applicant submits that one of ordinary skill in the art, upon reading Epstein et al. would not be motivated to substitute the filter of Dieck et al. for the occlusion membrane in Epstein's device because doing so would appear to destroy or at least significantly alter the purpose of the Epstein et al. method. Additionally, the Examiner's reason for modifying the Epstein et al. device, that of achieving a device that removes plaque and other material which can obstruct blood vessels, renders the Epstein et al. device unsatisfactory for its intended purpose of <u>occluding</u> a puncture site.

Applicant submits that when considered in its entirety, the Epstein et al. reference is directed to a device with an impermeable membrane for occlusion of a puncture site. Dieck et al. discloses an expandable intravascular filter. However, Applicant submits that there is no motivation for one of ordinary skill in the art to modify the method of Epstein et al. to expand the membrane to conform to the vessel lumen. Epstein et al. teach inserting the device through a puncture and expanding the impermeable membrane to seal the puncture. It appears that further expanding the membrane of the Epstein et al. device to conform to the vessel lumen would result in occlusion of the vessel, which is not the intent of Epstein et al. Even if one were to substitute the permeable filter of Dieck et al., there is no motivation to expand the filter to conform to the vessel lumen because doing so would not achieve the purpose of Epstein et al., i.e. sealing the puncture. Further, such a combination would not achieve the filtering purpose of Dieck et al. because Epstein et al. teaches the orientation of the device such that a permeable membrane would not be placed such that it would capture any debris.

Looking, for example, at FIG. 24 of Epstein et al., if the membrane were a filter of Dieck et al. and if the filter were expanded to conform to the vessel lumen, debris would collect on the surface of the filter, but when the expandable member was retracted and the filter collapsed, the debris would be released as there is no capturing means. Applicant submits that one of ordinary skill in the art would not be motivated to make such a modification of Epstein et al. because the modification would change the function and desired result of the method of Epstein et al.

MPEP 2143.01 states that if "the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being

P.09

Application No. 10/044,354 Reply to Office Action dated August 11, 2004

modified, then the teachings of the references are not sufficient to render the claims prima facie obvious," citing In re Ratti, 123 USPQ 349 (CCPA 1959). Applicant submits that substituting the filter of Dieck et al. for the blood-impermeable membrane of Epstein et al. would change the principle of the method taught by Epstein et al., by changing the occlusion method into a filtration method. The principles of operation of the Epstein et al. and Dieck et al. devices are completely opposite, thus modifying the occlusion device to have a filter would render the occlusion device unsuitable for its intended purpose in the occlusion method. Applicant submits that there is no motivation, either in Epstein et al., Dieck et al., or reasoned from knowledge generally available to one of ordinary skill in the art, for one to substitute the occlusion membrane of Epstein et al. with the filter of Dieck et al. As such, the only motivation for combining the teachings of Epstein et al. and Dieck et al. appears to come from the instant specification, which is improper. Applicant respectfully requests withdrawal of the rejection.

Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

tternev.

MARK T. UNGS

Date: 17, 7005

Glenn M. Seager, Reg. No. 36,926

CROMPTON, SEAGER & TUFTE, LLC

1221 Nicollet Avenue, Suite 800 Minneapolis, Minnesota 55403-2420

Tel: (612) 677-9050